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UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: MITANI, et al. Examiner: Unknown  
Serial No.: 10/583706 Group Art: Unknown  
Filed: June 20, 2006 Docket: 20078.0001USWO  
Confirmation No.: 4017 Notice of Allow Date: n/a  
Due Date: n/a  
Title: METHOD OF AMPLIFYING NUCLEIC ACID AND METHOD OF  
DETECTING MUTATED NUCLEIC ACID USING THE SAME

CERTIFICATE UNDER 37 CFR 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on September 20, 2006.

By:

Name: Peggy Kenchov

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

52835

PATENT TRADEMARK OFFICE

Sir:

The following papers are transmitted herewith:

- ☒ Transmittal Sheet in duplicate containing Certificate of Mailing
- ☒ Information Disclosure Statement, Form 1449, 54 references
- ☒ Other: Form PCT/IB/306
- ☒ Return Postcard

Please charge any additional fees or credit overpayment to Deposit Account No. 50-3478. A duplicate of this sheet is enclosed.

Hamre, Schumann, Mueller & Larson, P.C.  
P.O. Box 2902 Minneapolis, MN 55402-0902  
612.455-3800

By:

Name: Douglas P. Mueller  
Reg. No.: 30,300  
Initials: DPM/pjk

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Applicant: MITANI, et al.

Examiner: Unknown

Serial No.: 10/583,706

Group Art Unit: Unknown

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Docket: 20078.0001USWO

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By:

*Peggy Kerkhove*

Name: Peggy Kerkhove

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner. At least some of the references were recently cited in an International Search Report mailed April 12, 2005. A copy of the search report was included with the application papers filed on June 20, 2006. Copies of any foreign patent documents or "Other Documents" are enclosed.

A concise explanation of the relevance of each non-English language document or other information is as follows (37 C.F.R. §(a)(3)):

English abstracts have been included for JP 10-257900 and JP 59-93099. The following is a list of the cited reference and its English equivalent.

JP7-114718	US 5,712,124
JP 2651059	US 6,063,603
JP 2710159	US 6,420,539
WO 00/28082	US2002/168676
WO 02/166399	US 2003/073081
WO 01/34838	US 2002/168676
WO 02/24902	US 2004/038253
WO 99/54455	EP 1 072 678
JP4-501959	US 5,512,439
JP 7-6986	US 4,672,040
JP59-148798	US 4,849,336
JP 59-204200	US 4,849,336

JP2000-245460	EP 1 158 047 & EP 1 327 679
JP 9-504699	WO 95/12689
JP2000-300265	WO 00/63691
WO 99/06591	EP 1 041 160
WO 01/77317	US 2003/207292

In accordance with the provisions of 37 C.F.R. §1.97, this statement is being filed (CHECK ONE):

- ☒ (1) within three (3) months of the Filing Date, before the mailing date of a First Office Action on the merits, or before the mailing date of a First Office Action on the merits after the filing of a request for continued examination under 37 C.F.R. §1.114; or
- ☐ (2) after the period defined in (1) but before the mailing date of a Final Rejection or Notice of Allowance, and
- ☐ the requisite Statement is below, OR
- ☐ the requisite fee of \$180.00 under Rule 1.17(p) is included herein, or
- ☐ (3) after the mailing date of a Final Rejection or Notice of Allowance but on or before the payment of the Issue Fee, AND
- ☐ the requisite Statement is below, AND
- ☐ the requisite fee of \$180.00 under Rule 1.17(p) is included herein.

#### STATEMENT

As required under §1.97(e), Applicants hereby state either that:

- ☐ 1. Each item of information contained in the Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or
- ☐ 2. No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in §1.56(c) more than three months prior to the filing of the Information Disclosure Statement.
- ☐ If this box is checked, Applicant provides the following:

#### **Certification Under 37 C.F.R. §1.704(d)**

In accordance with 37 C.F.R. §1.704(d), the undersigned hereby certifies that each item listed on the enclosed Form 1449 was first cited in a communication from a foreign patent office in a counterpart application, and that this communication was

not received by any individual designated in 37 C.F.R. §1.56(c) more than thirty (30) days prior to the filing of this Information Disclosure Statement.

☐ The Examiner is hereby advised of the following co-pending U.S. applications. A copy of each U.S. patent application publication (if published) or application (if not published) is enclosed.

Application No.

Filing Date

Group

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

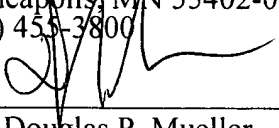
#### **FEE AUTHORIZATION**

Should any fee associated with the submission of this paper not be attached hereto as a check, the Commissioner is authorized to charge the missing fee to our Deposit Account, No. 50-3478. Any overpayments should be credited to said Deposit Account.

Respectfully submitted,

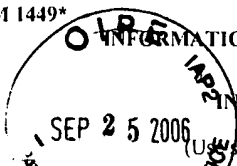
HAMRE, SCHUMANN, MUELLER &  
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(612) 455-3800

Dated: September 20, 2006

By:   
Douglas P. Mueller  
Reg. No. 30,300

DPM/pjk



<b>FORM 1449*</b>  <b>INFORMATION DISCLOSURE STATEMENT</b> <b>IN AN APPLICATION</b> (Use several sheets if necessary)	Docket Number: 20078.1USWO	Application Number: 10/583706
	Applicant: MITANI, et al.	
	Filing Date: June 20, 2006	Group Art Unit: Unknown

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,672,040	June, 1987	Josephson			
	4,683,195	July, 1987	Mullis, et al.			
	4,683,202	July, 1987	Mullis			
	4,800,159	January, 1989	Mullis, et al.			
	4,849,336	July, 1989	Miyoshi, et al.			
	5,512,439	April, 1996	Hornes, et al.			
	5,712,124	January, 1998	Walker			
	5,824,517	October, 1998	Cleuziat, et al.			
	6,046,807	April, 2000	Chandler			
	6,063,603	May, 2000	Davey, et al.			
	6,057,107	May, 2000	Fulton			
	6,366,354	April, 2002	Chandler			
	6,420,539	July, 2002	Kramer, et al.			
	2002/168676	November, 2002	Notomi, et al.			
	2003/73081	April, 2003	Mukai, et al.			
	6,617,106	September, 2003	Benner			
	2003/207292	November, 2003	Notomi, et al.			
	2004/038253	February 2004	Nagamine			

**FOREIGN PATENT DOCUMENTS**

	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	59-93099	May, 1984	Japan			Abstract	
	59-148798	August, 1984	Japan				
	59-204200	November, 1984	Japan				
	0 320 308	June, 1989	EPO				
	4-501959	April, 1992	Japan				

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.	

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	7-6986	January, 1995	Japan				
	95/12689	May, 1995	WIPO				
	95/25180	September, 1995	WIPO				
	7-114718	December, 1995	Japan				
	9-504699	May, 1997	Japan				
	2650159	May, 1997	Japan				
	2710159	October, 1997	Japan				
	10-257900	September, 1998	Japan			Abstract	
	99/06591	February, 1999	WIPO				
	99/09211	February, 1999	WIPO				
	99/10369	March, 1999	WIPO				
	99/54455	October, 1999	WIPO				
	00/28082	May, 2000	WIPO				
	2000-245460	September, 2000	Japan				
	1 041 160	October, 2000	EPO				
	00/63691	October, 2000	WIPO				
	2000-300265	October, 2000	Japan				
	1 072 678	January, 2001	EPO				
	01/034838	May, 2001	WIPO				
	01/077317	October, 2001	WIPO				
	1 158 047	November, 2001	EPO				
	02/16639	February, 2002	WIPO				
	02/24902	March, 2002	WIPO				
	1 327 679	July, 2003	EPO				

**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent Pages, Etc.)

	Larrick, James W., "Message Amplification Phenotyping (MAPPING) – principles, practice and potential", TIBTECH May 1992, vol. 10, 146-152
	Sambrook, et al., "Conditions for Hybridization of Oligonucleotide Probes", Molecular Cloning, 2 <sup>nd</sup> edition, Cold Spring Harbor Laboratory Press, pp. 11.45-11.57, 1989
	Horlacher, et al., "Recognition by viral and cellular DNA polymerases of nucleosides bearing bases with nonstandard

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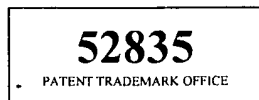
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	hydrogen bonding patterns", Proc. Natl. Acad. Sci. USA, vol. 92, pp. 6329-6333, July 1995
	Sismour, et al., "First PCR amplification of DNA containing a non-standard base pair", Biochemistry, vol. 42, no. 28, p. 8598, 2003
	Lutz, et al., "Recognition of a Non-Standard Base Pair by Thermostable DNA Polymerases", Bioorganic & Medicinal Chemistry Letters 8, pp. 1149-1152, 1998
	Gotoh, et al., "Rapid method for detection of point mutations using mismatch binding protein (MutS) and an optical biosensor", Genetic Analysis: Biomolecular Engineering, 14, pp. 47-50, 1997
	Deng, et al., Site-Directed Mutagenesis of Virtually any plasmid by Eliminating a Unique Site", Analytical Biochemistry 200, pp. 81-88, 1992
	Nakamaye, et al., "Inhibition of restriction endonuclease Nci I cleavage by phosphorothioate groups and its application to oligonucleotide-directed mutagenesis", Nucleic Acids Research, vol. 14, no. 24, pp. 9679-9698, 1986
	Diaz, et al., "PCR-Mediated Chemical Mutagenesis of Cloned Duplex DNAs", BioTechniques, vol. 11, no. 2, pp. 204-211, 1991
	Radman, et al., "Mismatch Repair in <i>ESCHERICHIA COLI</i> ", Ann. Rev. Genet., 20, pp. 523-538, 1986
	Radman, et al., "The High Fidelity of DNA Duplication", Scientific American, pp. 24-30, August 1988
	Modrich, Paul, "Methyl-directed DNA Mismatch Correction", The Journal of Biological Chemistry, vol. 264, no. 12, pp. 6597-6600, 1989
	Lahue, et al., PDNA Mismatch Correction in a Defined System", Science, vol. 245, pp. 160-164, July 1989
	Jiricny, et al., "Mismatch-containing oligonucleotide duplexes bound by the <i>E. coli mutS</i> -encoded protein", Nucleic Acids Research, vol. 16, no. 16, pp. 7843-7853, 1988
	Su, et al., "Mispair Specificity of Methyl-directed DNA Mismatch Correction <i>in Vitro</i> ", The Journal of Biological Chemistry, vol. 263, no. 14, pp. 6829-6835, May 1988
	Lahue, et al., "Methyl-directed DNA mismatch repair in <i>Escherichia coli</i> ", Mutation Research, 198, pp. 37-43, 1988
	Dohet, et al., "Large non-homology in heteroduplex DNA is processed differently than single base pair mismatches", Mol Gen Genet, 206, pp. 181-184, 1987
	Jones, et al., "Repair of a Mismatch is Influenced by the Base composition of the Surrounding Nucleotide Sequence", Genetics, 115, pp. 605-610, April 1987
	Lu, et al., "Repair of Single Base-Pair Transversion Mismatches of <i>Escherichia coli in Vitro</i> : Correction of Certain A/G Mismatches is Independent of <i>dam</i> Methylation and Host <i>mutHLS</i> Gene Functions", Genetics, 118, pp. 593-600, April 1988
	Haber, et al., "Nucleotide Sequence of the <i>Salmonella typhimurium mutS</i> Gene Required for Mismatch Repair: Homology of MutS and HexA of <i>Streptococcus pneumoniae</i> ", Journal of Bacteriology, vol. 170, no. 1, pp. 197-202, January 1988
	Pang, et al., "Identification and Characterization of the <i>mutL</i> and <i>mutS</i> Gene Products of <i>Salmonella typhimurium</i> LT2", Journal of Bacteriology, vol. 163, no. 3, pp. 1007-1015, September 1985
	Priebe, et al., "Nucleotide Sequence of the <i>hexA</i> Gene for DNA Mismatch Repair in <i>Streptococcus pneumoniae</i> and

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		Homology of <i>hexA</i> to <i>mutS</i> of <i>Escherichia coli</i> and <i>salmonella typhimurium</i> ", Journal of Bacteriology, vol. 170, no. 1, pp. 190-196, January 1988
		Smith, et al. Mutation detection with MutH, MutL, and MutS mismatch repair proteins, Proc. Natl. Acad. Sci. USA, vol. 93, pp. 4374-4379, April 1996
		Au, et al., "Initiation of Methyl-directed Mismatch Repair", The Journal of Biological Chemistry, vol. 267, no. 17, pp 12142-12148, June 1992
		Clark, et al., "Functional Interaction of Proliferating Cell Nuclear Antigen with HSH2-MSH6 and MSH2-MSH3 Complexes", The Journal of Biological Chemistry, vol. 275, no 47, pp. 36498-36501, November 2000



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